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EXAMINER
TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/021,168	Gorfine
Examiner	**Art Unit**
Christopher Tate	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 11, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *37-51* is/are pending in the application.

4a) Of the above, claim(s) *46-51* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *37-45* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election of Group I, claims 37-45, in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 37-45, newly presented in the preliminary amendment of Paper No. 2, are all drawn to a "kit" comprising multiple unit dosages of a semisolid pharmaceutical composition consisting essentially of a nitric oxide donor (nitroglycerin) as the active ingredient therein, wherein each unit dosage has nitroglycerin in an amount from about 0.05 mg to about 1000 mg within a range of 0.05-1000 mg (or various narrower mg ranges therein), and a container for storing and providing multiple unit dosages. However, the specification fails to provide any literal or implied support for this term/concept. Please note that a kit is typically used within the art to describe a package/container housing separately contained components therein.

As discussed in the 2/22/02 Office action of co-related Application No. 09/812,277, the passages noted on page 5 of the March 19, 2001 amendment within Appl. No. 09/812,277 which allegedly provide support for a "kit" (i.e., pages 15-16 and Examples 1-3) instead disclose containers having the final dosage form of the admixture of nitric oxide donor and carrier therein (i.e., squeeze tubes for lotions and ointments) or simply show how the admixture of 2% nitroglycerin in white petrolatum is further mixed/diluted with an additional amount of white petrolatum is prepared, which does not literally nor reasonably convey the concept of a "kit" containing separately housed components therein, as typically used in the art; nor of a kit composed of a container containing individual multiple unit dosages therein.

In addition, the mg unit dosage unit ranges of "about 0.05 mg to about 1000 mg" (claim 37), "about 0.05 mg" (claim 43), "about 1.7 to about 3.5 mg" (claim 44), and "about 2 to 5 mg" (claim 45) could not be found within the instant specification and are, therefore, deemed new matter. Further, claim 39 is drawn to the NO donor being "nitrous oxide". However, "nitrous oxide" (which is an odorless gas having the chemical name dinitrogen monoxide and the formula N_2O) as an NO donor could not be found in the instant specification and is, therefore, deemed new matter.

Applicant is required to cancel the claimed new matter in response to this Office action or, alternatively, to particularly point to support in the instant specification for the above new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is rendered vague and indefinite because it is unclear by the phrase "consisting essentially of a NO donor ... wherein each unit dosage ... has nitroglycerin" (lines 4-6). It is very unclear by this phrase if the NO donor is nitroglycerin or not, especially since claim 39 defines a different NO donor ("nitrous oxide"). Also the term "has" preceding "nitroglycerin" within this phrase does not clearly define if the composition does or does not contain nitroglycerin.

Claim 37 is also rendered vague and indefinite by the phrase "providing multiple unit dosages" (last line) because it is unclear if "multiple unit dosages" are referring to the "multiple unit dosages" defined in line 3 or to some other multiple unit dosages. It is suggested that the term --the-- be inserted between the words "providing" and "multiple" within this phrase to clarify this ambiguity.

Claims 38, 40, 43, 44, 45 are all drawn to the pharmaceutical composition further comprising an additional active ingredient therein, which is outside the limitations of claim 37 (from which these claims directly or indirectly depend) and, therefore, these claims are unclear and improper because in claim 37, the phrase "consisting essentially of a NO donor as the active

ingredient" is closed with respect to any additional active ingredients being incorporated in the claimed pharmaceutical composition.

Claim 39 is rendered vague and indefinite by the phrase "wherein the NO donor is nitrous oxide" because it appears to be outside the limitation of claim 37 (from which claim 39 depends) since claim 37 apparently defines the NO donor as being nitroglycerin.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37, 38, 40, 41 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Leslie et al. (US 4,654,209).

A kit comprising multiple unit dosages of a semisolid pharmaceutical composition consisting essentially of about 0.05 mg to about 1000 mg of an organic nitric oxide donor such as nitroglycerin, a pharmaceutically acceptable carrier, and a container for storing and providing multiple unit dosages is claimed.

Leslie et al. teach topically applied pharmaceutical ointment/cream compositions (thus, inherently within an applicator) in one gram unit dosages comprising different low level amounts of nitroglycerin therein (so as to avoid headaches), including 0.05 % (which is equivalent to 0.05 mg/gram dosage unit) to about 2 % (which is equivalent to 2 mg/gram dosage unit) by weight (see, e.g., col 7, line 15 - col 8, line 36), which are approximately within the mg ranges instantly claimed. Leslie also teaches that a steroid such as hydrocortisone and an analgesic (anesthetic) can also be incorporated therein (see, e.g., col 10, lines 4-20). The reference compositions would inherently and necessarily be contained within some type of container - which also constitutes a "kit"; and would inherently be composed of multiple unit dosages. Please also note that the instant claims read on final nitroglycerin preparations which have been admixed with a pharmaceutical carrier to achieve the claimed concentration of nitroglycerin therein because the claims do not require that the additional pharmaceutical carrier be separately housed therein.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 37, 41, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Loder et al. (Abstract: Gastroenterol., April 1993), Loder et al. (Abstract: Gut, March/April 1993), or Loder et al. (Abstract: Am Soc. Colon Rectal Surgs, April 1993).

Each of the Loder et al. references disclose a topically applied semisolid composition (thus, inherently within an applicator) containing the nitric oxide donor nitroglycerin as the active ingredient therein for treating anal conditions such as hemorrhoids and anal fissures, whereby 2%

nitroglycerin (GTN) is diluted 1:10 in a pharmaceutically acceptable carrier (i.e., soft yellow paraffin) so as to produce a topical pharmaceutical composition having a final nitroglycerin concentration of 0.2%, by weight (see abstracts). Such a composition would inherently and necessarily be contained within some type of container (e.g., so as to prepare the dilution, etc. - i.e., the nitroglycerin and ointment carrier would not be resting in air before, during, or after such dilution preparation but instead would be suitably placed within some type of container prior to application)- which also constitutes a "kit"; and would inherently be composed of multiple unit dosages, since only a small amount thereof would be used for applying to a subject in need thereof. Further, the amount of nitroglycerin per gram of each of the Loder compositions is 2 mg (0.2% of 1 gram). Please note that the typical amount of ointment used per dose (anal application) would be 1 gram or less and, thus, each topically applied unit dosage would inherently be within or approximately within the claimed mg amount ranges (however, the Loder references do not expressly teach inclusion of an anesthetic).

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claims 37 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Gregory et al. (USP 4,371,516), Babaian et al. (USP 4,842,854), or Nagy et al. (USP 5,047,230), and under U.S.C. 102(e) as being anticipated by Garfield et al. (USP 5,595,970).

Gregory teaches pharmaceutical compositions (containing pharmaceutical carriers) in and applicator unit dosage form comprising nitroglycerin as the active ingredient therein, wherein the

unit dosage contains 1 mg of nitroglycerin (see, e.g., cols 2-3, Example 2), which is approximately the mg ranges instantly claimed.

Babaian et al. teach anti-angina pharmaceutical compositions (containing pharmaceutical carriers) in an applicator unit dosage form comprising nitroglycerin (also called glycerol trinitrate) as the active ingredient therein, wherein the unit dosages contain 1-2 mg of nitroglycerin (see, e.g., col 15, lines 36-39, col 22, lines 1-3, col 23, lines 26-29, col 25, Table 3, and col 33, Example 13), which is approximately the mg ranges instantly claimed.

Nagy et al. teach pharmaceutical compositions (containing pharmaceutical carriers) in unit dosage form which can be within an applicator (aerosol) device comprising nitroglycerin as the active ingredient therein, wherein the unit dosage contains nitroglycerin within a concentration range of 0.1 to 12 mg (see, e.g., col 3, line 65 - col 4, line 2), which is approximately within the mg ranges instantly claimed.

Garfield et al. teach pharmaceutical compositions (containing pharmaceutical carriers) in an applicator unit dosage form comprising nitroglycerin as the active ingredient therein, wherein the unit dosages contain nitroglycerin which are approximately within the mg ranges instantly claimed (see, e.g., col 4, lines 48-65).

The cited compositions would each inherently and necessarily be contained within some type of container - which also constitutes a "kit", and would inherently be composed of multiple unit dosages (however, none of the cited references expressly teach inclusion of an anesthetic).

Therefore, the references are each deemed to anticipate the instant claims above.

Claims 37, 41, and 42 are rejected under U.S.C. 102(e) as being anticipated by Snyder et al. (USP 5,439,938).

Snyder et al. teach pharmaceutical compositions (containing pharmaceutical carriers) in unit dosage form which can be in a topical form such as a lotion, cream, salve, ointment, as well as within an applicator (injection) device (see, e.g., col 3, lines 29-33) comprising nitroglycerin as the active ingredient therein, wherein each unit dosage contains about 0.01 to about 10 mg nitroglycerin (see, e.g., col 4, lines 36-48) and, thus, approximately within the mg ranges instantly claimed (however, Snyder et al. do not expressly teach inclusion of an anesthetic). The reference compositions would inherently and necessarily be contained within some type of container - which also constitutes a "kit"; and would inherently be composed of multiple unit dosages.

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37, 38, 40, 42, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babaian et al. (USP 4,842,854) in view of Emmett et al. (USP 4,657,906).

The pharmaceutical composition further comprising a topical anesthetic or corticosteroid is also claimed.

Babaian et al. is relied upon for the reasons discussed *supra.* Babaian et al. do not teach the inclusion of a topical anesthetic in their pharmaceutical compositions comprising nitroglycerin.

Emmett et al. disclose that it is well known in the art to combine anti-anginal agents such as glyceryl trinitrate (nitroglycerin) with anti-arrhythmic agents such as lignocaine, a well known topical anesthetic, within pharmaceutical unit dose compositions (see, e.g., col 4, lines 1-41), as both are art-recognized as providing beneficial effects to the heart.

It would have been obvious to further advantageously include a topical anesthetic such as lignocaine to the pharmaceutical composition of Babaian et al. because, as evidenced by Emmett et al., this combination is well recognized in the art to provide broad beneficial effects to the heart. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 37, 38, and 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leslie et al. (USP 4,654,209), in view of Poser (USP 4,683,242).

Leslie et al. teach topically applied pharmaceutical ointment compositions (thus, in an applicator) comprising at least 0.05% nitroglycerin as the essential bioactive ingredient therein, and an addition medicament including a steroids such as hydrocortisone (see, e.g., col 10, lines 12-16) and/or analgesics (anesthetic), wherein the nitroglycerin beneficially acts to enhance the bioavailability of the additional medicament (see, e.g., abstract, col 3, lines 1-19). Leslie also teaches that increased concentrations of nitroglycerin caused headaches (see, e.g., col 8, lines 10-22). Leslie et al. disclose that topical ointments of this kind typically are applied in dosages of 1 gram (see, e.g., col 1, lines 21-26 and 54-59, and claims 1, 5, 6, 7, and 15). A one-gram dosage of the Leslie et al. topical ointment comprising 0.05%-0.25% nitroglycerin would, thus, contain .05-2.5 mg nitroglycerin. As evidenced by Poser (see, e.g., col 22, lines 12-27, for convenience and as a matter of safety - to avoid headaches, etc.), advantageously adapting/dividing topical ointment compositions, such as those taught by Leslie et al., into common art-accepted multiple unit dosage forms (e.g. foil packets) - each containing nitroglycerin within the claimed concentration range.

The inclusion of a conventionally employed applicator (e.g., a cotton stick applicator, gauze, towelette, tissue, or plastic/rubber barrier such as gloves) so as to conveniently apply the topical composition without exposing the hands to the lipophilic ointment or nitroglycerin taught by Leslie (and, thus, avoid the need of washing the hands afterward as well as to avoid potential headaches from exposure to the nitroglycerin) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 37-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loder et al. (Abstract: Gut, March 1993), Loder et al. (Abstract: Am Soc. Colon Rectal Surgs, April 1993), and Guillemot et al. (Abstract: Dis. Colon Rectum, 1993), in view of Gallina (US 4,514,384), and further in view of Fung et al. (Am. J. Cardiol., 1992) as well as the recognized state of the art.

The Loder et al. references are relied upon for the reasons discussed *supra*. The diluted nitroglycerin ointment composition taught by Loder et al. was used so as to avoid severe headaches known to be caused by stronger nitroglycerin preparations (see abstracts). In a pilot study, Guillemot et al. also teach the use of a topical composition (which is applied via a balloon applicator) comprising 5 mg nitroglycerin as an active ingredient therein which may be useful in treating anal conditions such as anal fissures. Guillemot et al. expressly caution that, although they used 5 mg of nitroglycerin in this pilot study, it might be of value to try different doses of nitroglycerin since 5 mg "might be an excessive dose concerning the anal sphincter" (see, e.g., abstract and pages 374-375). In particular, some patients in their pilot program still suffered from headaches and lipothymia (faintness), most likely due to art-recognized low blood pressure risks associated with excess nitroglycerin absorption.

The Loder et al. and Guillemot et al. references do not expressly teach the inclusion of a corticosteroid or topical anesthetic, nor using other conventional vasodilating organic nitrates (nitric oxide donors) instead of nitroglycerin.

Gallina teaches topical pharmaceutical preparations for treating hemorrhoids and healing rectal tissue that beneficially comprise hydrocortisone (i.e., to reduce inflammation) and a topical anesthetic such as dibucaine (i.e., to reduce pain) [see, e.g., col 1, line 61 - col 2, line 68]. In addition, as readily admitted by applicant, the beneficial use of these two agents within anal therapeutic preparations is well recognized in the art (see, e.g., specification, page 3, last paragraph, and page 6, last two paragraphs).

Fung et al. teach that art-recognized chemically related vasodilating organic nitrates such as claimed are known producers of nitric oxide, i.e. - nitric oxide donors (see entire document). Also, please note, as readily admitted by applicant, the group of organic nitrates recited on page 6 of the instant specification (first full paragraph) are all notoriously well known to be close chemically-related vasodilating compounds which are often used interchangeably in the art. Accordingly, the substitution of nitroglycerin (as taught by Loder et al.) for another well known chemically related vasodilating organic nitrate (e.g., nitrous oxide) would have been obvious to the skilled artisan as they are all well known in the art to be essentially equivalent and, thus, interchangeable.

Based upon the reference teachings above, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a kit (e.g., a tube, bottle, or other common pharmaceutical ointment container) containing multiple unit dosages of nitroglycerin (or other art-recognized equivalent interchangeable nitric oxide donor such as nitrous oxide) within the claimed approximate dosage ranges therein and a pharmaceutically acceptable carrier (such as yellow paraffin or white petrolatum which are both notoriously well known in the art to be effective, commonly employed topical ointment carriers), so as to provide a composition containing further diluted nitroglycerin therein (such as beneficially disclosed by Loder et al.). The adjustment in the concentration range of nitroglycerin (or other art-recognized equivalent nitric oxide donor) within such topical compositions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, based upon the beneficial teachings provided by the primary references of Loder et al. and/or Guillemot et al. with respect to beneficially incorporating result-effective low concentrations of nitroglycerin therein so as to avoid well known art-recognized side effects (e.g., headaches and/or lipothymia) associated with *in vivo* absorption of this active ingredient. Further, with regard to the further inclusion of a corticosteroid (e.g., hydrocortisone) and an anesthetic (e.g., dibucaine) to the Loder et al. topical hemorrhoidal preparation.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose (i.e., the beneficial agents within topical hemorrhoidal preparations such as those disclosed by Loder et al.,Guillemot et al.,

and Gallina - discussed above) in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

The conventional use of applicators (e.g., anal insertion tubes/devices, cotton stick applicators, gauzes, tissues, towelettes, plastic/rubber barriers for hands such as gloves, to name a few) to conveniently and effectively apply such topical therapeutic compositions to the anus/anal canal, as well as to safely protect the hands from direct exposure thereto, is notoriously well known and accepted in the art. Accordingly, the inclusion of an applicator within such a kit would have been well within the purview of the skilled artisan as a mere matter of routine optimization in providing an art-accepted means for the safe and efficient delivery of the reference topical nitroglycerin compositions. Further, for convenience and safety, adapting/ dividing such topical compositions into common art-accepted unit dosage forms (e.g., foil packets, suppositories, etc.) - each containing nitroglycerin within the claimed concentration range, based upon the beneficial teachings provided by the Loder et al. and Guillemot et al. references, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the admitted state of the art, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record (in this application and in parent applications) and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.

Christopher R. Tate
Primary Examiner, Group 1654